COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 27-IX-2004
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NOT FOR PUBLICATION

COMMISSION DECISION

of 27-IX-2004

granting marketing authorisation for the medicinal product for human use "Apidra - Insulin glulisine" under Council Regulation (EEC) No 2309/93

(Text with EEA relevance)

ONLY THE GERMAN TEXT IS AUTHENTIC

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(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products[1], as amended by Commission Regulation (EC) No 649/98[2], and in particular Article 10(2) thereof,

Having regard to the application submitted by Aventis Pharma Deutschland GmbH, on 23 June 2003, under Article 4(1) of Regulation (EEC) No 2309/93,

Having regard to the opinion of the European Medicines Agency, formulated by the Committee for Medicinal Products for Human Use on 3 June 2004,

Whereas:

(1) The medicinal product "Apidra - Insulin glulisine" complies with the requirements set out in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[3] as amended by Directive 2002/98/EC[4] and by Directive 2003/63/EC[5].

(2) It is therefore appropriate to authorise its placing on the market.

(3) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Medicinal Products for Human Use,

[1] OJ L 214, 24. 8. 1993, p. 1.
[2] OJ L 88, 24.3.1998, p. 7.
[3] OJ L 311, 28.11.2001, p. 67.
[4] OJ L 33, 8.2.2003, p. 30.
[5] OJ L 159, 27.6.2003, p. 46.

HAS ADOPTED THIS DECISION:

Article 1

The marketing authorization referred to in Article 3 of Regulation (EEC) No 2309/93 is hereby granted in respect of the medicinal product, "Apidra - Insulin glulisine" whose characteristics are summarized in Annex I hereto. This medicinal product shall be entered in the Community Register of Medicinal Products under the numbers:

EU/1/04/285/001	Apidra-100 U/ml-Solution for injection-Subcutaneous use-vial (glass)-10 ml -1 vial
EU/1/04/285/002	Apidra-100 U/ml-Solution for injection-Subcutaneous use-vial (glass)-10 ml - 2 vials
EU/1/04/285/003	Apidra-100 U/ml-Solution for injection-Subcutaneous use-vial (glass)-10 ml -4 vials
EU/1/04/285/004	Apidra-100 U/ml-Solution for injection-Subcutaneous use-vial (glass)-10 ml - 5 vials
EU/1/04/285/005	Apidra-100 U/ml-Solution for injection-Subcutaneous use-cartridge (glass)-3 ml -1 cartridge
EU/1/04/285/006	Apidra-100 U/ml-Solution for injection-Subcutaneous use-cartridge (glass)-3 ml -3 cartridge
EU/1/04/285/007	Apidra-100 U/ml-Solution for injection-Subcutaneous use-cartridge (glass)-3 ml -4 cartridges
EU/1/04/285/008	Apidra-100 U/ml-Solution for injection-Subcutaneous use-cartridge (glass)-3 ml -5 cartridges
EU/1/04/285/009	Apidra-100 U/ml-Solution for injection-Subcutaneous use-cartridge (glass)-3 ml -6 cartridges
EU/1/04/285/010	Apidra-100 U/ml-Solution for injection-Subcutaneous use-cartridge (glass)-3 ml -8 cartridges
EU/1/04/285/011	Apidra-100 U/ml-Solution for injection-Subcutaneous use-cartridge (glass)-3 ml -9 cartridges
EU/1/04/285/012	Apidra-100 U/ml-Solution for injection-Subcutaneous use-cartridge (glass)-3 ml -10 cartridges
EU/1/04/285/013	Apidra -100 U/ml-Solution for injection-Subcutaneous use-pre-filled pen (glass) (OptiSet)-3 ml -1 pre-filled pen
EU/1/04/285/014	Apidra -100 U/ml-Solution for injection-Subcutaneous use-pre-filled pen (glass) (OptiSet)-3 ml -3 pre-filled pens

EU/1/04/285/015	Apidra -100 U/ml-Solution for injection-Subcutaneous use-pre-filled pen (glass) (OptiSet)-3 ml -4 pre-filled pens
EU/1/04/285/016	Apidra -100 U/ml-Solution for injection-Subcutaneous use-pre-filled pen (glass) (OptiSet)-3 ml -5 pre-filled pens
EU/1/04/285/017	Apidra -100 U/ml-Solution for injection-Subcutaneous use-pre-filled pen (glass) (OptiSet)-3 ml -6 pre-filled pens
EU/1/04/285/018	Apidra -100 U/ml-Solution for injection-Subcutaneous use-pre-filled pen (glass) (OptiSet)-3 ml -8 pre-filled pens
EU/1/04/285/019	Apidra -100 U/ml-Solution for injection-Subcutaneous use-pre-filled pen (glass) (OptiSet)-3 ml -9 pre-filled pens
EU/1/04/285/020	Apidra -100 U/ml-Solution for injection-Subcutaneous use-pre-filled pen (glass) (OptiSet)-3 ml -10 pre-filled pens

Article 2

The marketing authorization concerning the medicinal product referred to in Article 1 shall be subject to compliance with all the conditions, particularly those relating to manufacture and importation, control and issue referred to in Annex II.

Article 3

The labelling and package leaflet concerning the medicinal product referred to in Article 1 shall conform to Annex III.

Article 4

The period of validity of the authorization issued shall be five years from the date of notification of this Decision. It shall be renewable under the conditions laid down in Article 13(1) of Regulation (EEC) No 2309/93.

Article 5

This Decision is addressed to Aventis Pharma Deutschland GmbH, Brueningstrasse 50, D-65926 Frankfurt am Main, Deutschland.

Done at Brussels, 27-IX-2004

For the Commission
Olli REHN
Member of the Commission